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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/626,366	07/24/2000	Cathy Ilyse Hess	D4857-00006	7385

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EXAMINER

FRENEL, VANEL

ART UNIT	PAPER NUMBER
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3626

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/626,366

Applicant(s)

HESS, CATHY ILYSE

Examiner

Vanel Frenel

Art Unit

3626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(h).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 3626

DETAILED ACTION

Notice to Application

1. This communication is in response to the RCE filed 08/01/03. Claims 1, 9, 15 have been amended. Claim 17 has been added. Claims 1-17 are pending.

Continued Prosecution Application

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 08/01/03 has been entered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dang (6,370,511) in view of Hennessy et al (6,277,071), and further in view of Gibson et al (6,077,082).

Art Unit: 3626

(A) As per claim 1, Dang and Hennessy disclose a computer-implemented method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) gathering patient care data and diagnosing a malady (See Dang, Col.9, lines 21-61);

(B) storing said patient care data and said diagnosis of said malady in a data storage means as a data record (See Dang, Col.12, lines 40-67);

(C) identifying an appropriate clinical pathway to follow in treating said diagnosed malady from a plurality of clinical pathways stored in said data storage means (See Dang, Col.12, lines 27-67 to Col.13, line 27);

(D) implementing said identified clinical pathway and recording each clinical action taken by a clinician as data record in said data storage means (See Dang, Col.12, lines 27-67).

monitoring and comparing said recorded clinical actions taken by said clinician to said identified clinical pathway so as to identify one or more variations from said identified clinical pathway (See Hennessy Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56).

Dang and Hennessy do not collectively disclose issuing an alert notice to said clinician at the time of performance of said identified clinical action identified as a variance from said identified appropriate clinical pathway so as to allow said clinician to alter said clinical action.

Art Unit: 3626

However, this feature is known in the art, as evidenced by Gibson. In particular, Gibson suggests issuing an alert notice to said clinician at the time of performance of said identified clinical action identified as a variance from said identified appropriate clinical pathway (See Gibson, Col.1, lines 22-51; Col.2, lines 7-67; Col.3, lines 1-67 to Col.4, line 43).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Gibson within the collective teachings of Dang and Hennessy with the motivation of providing a fairly realistic real-time representation of a doctor–patient relationship which can be generated in software and implemented on a personal computer (See Gibson, Col.1, lines 40-50).

(B) As per claim 2, Hennessy discloses a method according wherein said gathering of said patient care data includes applying a risk assessment tool comprising a rating scale to objectively characterize the subjective condition of said patient's skin and wound (See Hennessy Fig.20; Col.10, lines 29-60).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 1, and incorporated herein.

(C) As per claim 3, Hennessy discloses a method according wherein said rating scale identifies factors most closely associated with the formation of a selected malady (Col.2, lines 36-67 to Col.3, line 8).

Art Unit: 3626

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 1, and incorporated herein.

(D) As per claim 4, Hennessy discloses a method wherein said factors are associated with parameters that are identified and assessed by said clinician, and a rating number assigned to each of said parameters that corresponds to said clinician's objective assessment of a wound/skin condition (See Hennessy Fig.20; Col.10, lines 1-60).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 1, and incorporated herein.

(E) As per claim 5, Hennessy discloses a method wherein a finite numerical score is selected from a preselected range and assigned to each of said parameters (Col. 9, lines 29-63).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 1, and incorporated herein.

(F) As per claim 6, Hennessy discloses a method wherein a numerical score at or above a preselected value is indicative of a high risk for development of said malady (Col.9, lines 64-67 to Col.10, line 23).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 1, and incorporated herein.

Art Unit: 3626

(G) As per claim 7, Hennessy discloses a method wherein said parameters, along with their assigned scores, are stored at a known, searchable, and retrievable location in said data storage means (Col.9, lines 29-63).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 1, and incorporated herein.

(H) As per claim 8, Hennessy discloses a method wherein said monitoring includes reviewing each of said parameters, and identifying a most likely course of intervention to be followed by said clinician (Col.11, lines 1-45).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 1, and incorporated herein.

(I) As per claim 9, Dang discloses a computer-implemented method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) gathering patient care data and diagnosing a malady (See Dang, Col.9, lines 21-61);

(B) storing said patient care data and said diagnosis of said malady in a data storage means of a general purpose computer as a data record (See Dang, Col.12, lines 40-67);

Art Unit: 3626

(C) identifying an appropriate clinical pathway to follow in treating said diagnosed malady from a plurality of clinical pathways stored in said data storage means (See Dang, Col.12, lines 27-67 to Col.13, line 27);

(D) implementing said identified clinical pathway and recording each clinical action taken by a clinician as a data record in said data storage means (See Dang, Col.12, lines 27-67).

monitoring and comparing said recorded clinical actions taken by said clinician to said identified clinical pathway so as to identify one or more variations from said identified clinical pathway (See Hennessy Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56).

Dang does not explicitly disclose issuing an alert notice to said clinician of an identified variation from said identified clinical pathway at the time of performance of said clinical action identified as a variance so as to allow said clinician to alter said clinical action.

However, this feature is known in the art, as evidenced by Gibson. In particular, Gibson suggests issuing an alert notice to said clinician of an identified variation from said identified clinical pathway at the time of performance of said clinical action identified as a variance so as to allow said clinician to alter said clinical action (See Gibson, Col.1, lines 22-51; Col.2, lines 7-67; Col.3, lines 1-67 to Col.4, line 43).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Gibson within the collective teachings of Dang and Hennessy with the motivation of providing a fairly

Art Unit: 3626

realistic real-time representation of a doctor–patient relationship which can be generated in software and implemented on a personal computer (See Gibson, Col.1, lines 40-50).

(J) As per claim 10, Hennessy discloses a method wherein said gathering of said patient care data includes observing and recording a patient's vital signs (Col.7, lines 26-51).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 9, and incorporated herein.

(K) As per claim 11, Hennessy discloses a method wherein said recorded vital signs are each compared to a preselected value for said vital sign and monitored for deviations that are indicative of a high risk for development of a skin malady (See Hennessy Fig.20; Col.10, lines 1-60).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 9, and incorporated herein.

(L) As per claim 12, Hennessy discloses a method wherein said implementing said identified clinical pathway and recording clinical actions taken by said clinician includes implementing a skin and wound care regimen (Col.2, lines 1-35; Col.6, lines 30-67).

Art Unit: 3626

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 9, and incorporated herein.

(M) As per claim 13, Hennessy discloses a method wherein said skin and wound care regimen are monitored for deviations that are indicative of a high risk for deterioration of said skin and wound (Col.6, lines 12-67).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 9, and incorporated herein.

(N) As per claim 14, Hennessy discloses a method wherein said regimen comprises selection and application of dressings to a wound (See Hennessy Fig.20; Col.6, lines 30- 67).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 9, and incorporated herein.

(O) Claim 15 differs from claims 1 and 9 by reciting a method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) gathering patient care data according to a predetermined regimen for diagnosing a malady of the skin; (B) storing said patient care data in a data storage means of a general purpose computer.

Art Unit: 3626

As per this limitation, it is noted that Dang discloses (C) identifying an appropriate clinical pathway from a plurality of pathways for treating said diagnosed malady

(Col.12, lines 27-67 to Col.13, line 27);

(D) implementing said identified clinical pathway via clinical actions taken by a

clinician (Col.12, lines 27-67) and Hennessy discloses monitoring said clinical actions taken by said clinician to determine variations from said identified clinical pathway

(See Hennessy, Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56); and Gibson discloses issuing an alert notice to said clinician of an identified

variation from said identified clinical pathway at the time of performance of said clinical action identified as a variance so as to allow said clinician to alter said clinical action

(See Gibson, Col.1, lines 22-51; Col.2, lines 7-67; Col.3, lines 1-67 to Col.4, line 43).

Thus, it is readily apparent that these prior art systems utilize a predetermined regimen to perform their specified function.

The remainder of claim 15 is rejected for the same reason given above for claims 1 and 9, and incorporated herein.

(P) As per claim 16, Hennessy discloses a method wherein said regimen comprises answering a questionnaire that quantifies a patient's satisfaction with his/her health status (See Hennessy Col.2, lines 8-35).

The motivation for combining the respective teachings of Dang, Hennessy and Gibson are as discussed above in the rejection of claim 15, and incorporated herein.

Art Unit: 3626

(Q) As per claim 17, Dang discloses disclose a computer-implemented method for assessing deviations from a preselected medical treatment that has been indicated by appropriate diagnosis from a clinician, comprising the steps of:

(A) gathering patient care data and diagnosing a malady (See Dang, Col.9, lines 21-61);

(B) storing said patient care data and said diagnosis of said malady in a data storage means as a data record (See Dang, Col.12, lines 40-67);

(C) identifying an appropriate clinical pathway to follow in treating said diagnosed malady from a plurality of clinical pathways stored in said data storage means (See Dang, Col.12, lines 27-67 to Col.13, line 27);

(D) implementing said identified clinical pathway and recording each clinical action taken by a clinician as data record in said data storage means (See Dang, Col.12, lines 27-67).

monitoring and comparing said recorded clinical actions taken by said clinician, while said clinician is treating said patient, to said identified clinical pathway so as to identify one or more variations from said identified clinical pathway (See Hennessy Col.5, lines 30-67 to Col.6, line 51; Col.9, lines 64-67 to Col.10, line 56).

Dang and Hennessy do not collectively disclose issuing an alert notice to said clinician at the time of performance of said identified clinical action identified as a variance from said identified appropriate clinical pathway so as to allow said clinician to alter said clinical action.

Art Unit: 3626

However, this feature is known in the art, as evidenced by Gibson. In particular, Gibson suggests issuing an alert notice to said clinician at the time of performance of said identified clinical action identified as a variance from said identified appropriate clinical pathway (See Gibson, Col.1, lines 22-51; Col.2, lines 7-67; Col.3, lines 1-67 to Col.4, line 43).

It would have been obvious to one of ordinary skill in the art at the time of the invention to have included the features of Gibson within the collective teachings of Dang and Hennessy with the motivation of providing a fairly realistic real-time representation of a doctor–patient relationship which can be generated in software and implemented on a personal computer (See Gibson, Col.1, lines 40-50).

Response to Arguments

5. Applicant's arguments filed 08/01/03 regarding claims 1-16 have been fully considered but are moot in view of the new ground (s) of rejection. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 08/01/03.

(A) At page 9-14 of the 08/01/03 response, Applicant apparently argues that a prima facie of obviousness has not been established.

In response, all of the limitations which Applicant disputes as missing in the applied references, including the features newly added in the 08/01/03 amendment, have been fully addressed by the Examiner as either being fully disclosed or obvious in view of the collective teachings of Dang, Hennessy and/or Gibson based on the logic

Art Unit: 3626

and sound scientific reasoning of one ordinarily skilled in the art at the time of the invention, as detailed in the remarks and explanations given in the preceding sections of the present Office Action and in the prior Office Action (paper number 11), and incorporated herein. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In addition, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The cited but not applied art teaches three step wound treatment method and dressing therefor (4,813,942), system and method for managing patient medical records (5,772,585), medical system and associated method for automatic treatment (5,544,651) and skin patch for use in contact immunotherapy (5,846,559). Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanel Frenel whose telephone number is 703-305-4952. The examiner can normally be reached on 6:30am-5:00pm.


Art Unit: 3626

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on 703-305-9643. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-7687 for regular communications and 703-305-7687 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1113.

V.F
V.F

October 16, 2003


JOSEPH THOMAS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3600